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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,139	03/15/2004	Paul Haefner	GUID.609PA	9243

51294 7590 07/27/2007

HOLLINGSWORTH & FUNK, LLC
8009 34TH AVE S.
SUITE 125
MINNEAPOLIS, MN 55425

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
07/27/2007	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/801,139
Filing Date: March 15, 2004
Appellant(s): HAEFNER, PAUL

Erin M. Nichols
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/22/2007 appealing from the Office action mailed 5/4/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,867,163	Schaldach	9-1989
6,477,406	Turcott	11-2002

5,935,081	Kadhiresan	8-1999
5,321,618	Gessman	6-1994
2002/0026223	Riff	2-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim	Limitation	Disclosure of limitation in Schaldach (US 4,867,163)
1	An implantable device comprising:	A schematic representation of the device is shown in Figure 1, the implantable componentry denoted by 160 and 110.
	An implantable housing	The implantable housing is shown in Figure 1 as element 160.
	A plurality of implantable electrodes coupled to the housing and configured for sensing cardiac electrical activity	The plurality of implantable electrodes are shown as "A" and "V" on element 111 in Figure 1 and described at column 8, lines 25-28.
	Detection circuitry provided in the housing and coupled to at least some of the plurality of electrodes, the detection circuitry producing a cardiac electrical signal in response to the sensed cardiac electrical activity	The detection circuitry is shown as, e.g., element 509 in Figure 5 and described at column 21, lines 4-8.
	An implantable sensor configured to sense movement of a heart and produce a sensor signal in response to the sensed heart movement	The movement sensor, in the form of "sound pickups", is described at column 7, lines 61-68. Further these pickups sense heart movement or "mechanical contractions".
	Sensor circuitry provided in the housing and coupled to the sensor, the sensor circuitry configured to produce an audio signal in response to the sensor signal	Figure 1 shows the circuitry as elements 116-124.
	Memory provided in the housing and coupled to the detection circuitry and sensor circuitry, the memory configured to store the audio signal and the cardiac electrical signal	The memory is shown as element 112 in Figure 1 and described at column 8, lines 39-43.
	A controller provided in the housing	The controller is shown as element 113

	and coupled to the memory, detection circuitry, and sensor circuitry	in Figure 1.
	Communications circuitry provided in the housing and coupled to the controller, the communications circuitry configured to telemeter the cardiac electrical signal and the audio signal to a patient-external device	The communications circuitry is shown as element 116 and described at column 8, lines 19-24. The cardiac electrical signal and audio signal (or "physiological measured" or "input variables" of column 8, line 6) are telemetered to a patient-external device at column 23, lines 20-45.
17	A medical system comprising:	
	A patient implantable device comprising:	A schematic representation of the device is shown in Figure 1, the implantable componentry denoted by 160 and 110.
	A housing	The implantable housing is shown in Figure 1 as element 160.
	A plurality of electrodes coupled to the housing and configured for sensing cardiac electrical activity	The plurality of implantable electrodes are shown as "A" and "V" on element 111 in Figure 1 and described at column 8, lines 25-28.
	Detection circuitry provided in the housing and coupled to at least some of the plurality of electrodes, the detection circuitry producing a cardiac electrical signal in response to the sensed cardiac electrical activity	The detection circuitry is shown as, e.g., element 509 in Figure 5 and described at column 21, lines 4-8.
	A sensor configured to sense movement of a heart and produce a sensor signal in response to the sensed heart movement	The movement sensor, in the form of "sound pickups", is described at column 7, lines 61-68. Further these pickups sense heart movement or "mechanical contractions".
	Sensor circuitry provided in the housing and coupled to the sensor, the sensor circuitry configured to produce an audio signal in response to the sensor signal	Figure 1 shows the circuitry as elements 116-124.
	Memory provided in the housing and coupled to the detection circuitry and sensor circuitry, the memory configured to store the audio signal and the cardiac electrical signal	The memory is shown as element 112 in Figure 1 and described at column 8, lines 39-43.
	A controller provided in the housing	The controller is shown as element 113

	and coupled to the memory, detection circuitry, and sensor circuitry	in Figure 1.
	Communications circuitry provided in the housing and coupled to the controller, the communications circuitry configured to telemeter the cardiac electrical signal and the audio signal	The communications circuitry is shown as element 116 and described at column 8, lines 19-24. The cardiac electrical signal and audio signal (or "physiological measured" or "input variables" of column 8, line 6) are telemetered to a patient-external device at column 23, lines 20-45.
	A patient external device comprising:	The external device is shown schematically as elements 125 and 150 in Figure 1.
	Patient-external communications circuitry configured to receive the cardiac electrical signal and the audio signal telemetered from the patient-implantable device	The communications circuitry is shown as, e.g., elements 125, 151 and 155 in Figure 1, and described textually at column 23, lines 20-45.
	A user interface coupled to the patient-external communications circuitry, the user interface configured for providing a visual output representative of the cardiac electrical signal and an audio output representative of the audio signal	The user interface is shown as elements 157 and 158 in Figure 1, and described at column 23, line 24.
30	Wherein at least one of the patient-implantable device and patient-external device provides time correlation between the cardiac electrical signal and the audio signal	The time correlation is described at column 23, line 46 to column 24, line 16.
32	A method comprising:	
	Sensing, from within a patient, movement of a heart and producing a sensor signal in response to the sensed heart movement	The plurality of implantable sensing electrodes are shown as "A" and "V" on element 111 in Figure 1 and described at column 8, lines 25-28.
	Producing, within the patient, an audio signal using the sensor signal	A movement sensor, in the form of "sound pickups", is described at column 7, lines 61-68.
	Detecting, within the patient, cardiac electrical activity and producing a cardiac electrical signal in response to the detected cardiac electrical activity	The detection circuitry is shown as, e.g., element 509 in Figure 5 and described at column 21, lines 4-8.

	Storing, within the patient, the audio signal and the cardiac electrical signal	The memory for storing is shown as element 112 in Figure 1 and described at column 8, lines 39-43.
	Telemetering the audio signal and the cardiac electrical signal to a patient-external location	The communications circuitry is shown as element 116 and described at column 8, lines 19-24. The cardiac electrical signal and audio signal (or "physiological measured" or "input variables" of column 8, line 6) are telemetered to a patient-external device at column 23, lines 20-45.
35	Wherein the sensor comprises an accelerometer signal	The accelerometer is disclosed at column 7, lines 60-61 (i.e. "pressure or sound pickups") and column 20, line 68 (i.e. "microphone").
38	Wherein storing comprises time correlating the audio signal and the cardiac electrical signal	The time correlation is described at column 23, line 46 to column 24, line 16.

Claims	**Limitation lacking explicit disclosure from Schaldach (US 4,867,163)**	**Teaching from secondary reference**	**Motivation to combine the primary and secondary references**
17	A user interface coupled to the patient-external communications circuitry, the user interface configured for providing...an audio output representative of the audio signal.	Well known teachings in the art to provide audio output, e.g., US 5,010,889, 5,737,429, and 4,220,160.	To quickly diagnose cardiac pathology by ear.
4 and 36	Wherein the sensor comprises a piezoelectric transducer.	Turcott (US 6,477,406) teaches of using an implanted piezoelectric transducer (col. 10, line 17).	To provide a mechanical to electrical transducer (col. 10, line 13) sensitive to the desired frequency band (col. 10, lines 30-33).
8, 11, and 40	Wherein the plurality of electrodes is configured for subcutaneous, non-intrathoracic placement	Kadhiresan (US 5,935,081) teaches of providing cardiac electrodes to a subcutaneous, non-	To simplify implantation and maximize signal-to-noise (col. 2, lines 55-62).

		intrathoracic placement (col. 2, line 59).	
14	Wherein the cardiac therapy comprises cardiac defibrillation therapy.	Gessman (US 5,321,618) teaches of providing cardiac defibrillation therapy (abstract).	To treat a variety of potentially life-threatening arrhythmias (col. 1, lines 15-22).
18	Wherein the user interface is configured for providing an audio output representative of the cardiac electrical signal.	Gessman (US 5,321,618) teaches of providing an audio output representing a cardiac electrical signal (abstract).	To transfer the signal in a way that is perceivable by humans (col. 1, lines 36-53).
22 and 33	Wherein the communications circuitry is configured to telemeter the cardiac electrical signal and the audio signal from the patient-implantable device to the patient-external device in response to a user request.	Gessman (US 5,321,618) teaches of providing transmission in response to a user request at column 4, lines 57-65.	To allow transmission at a time that is convenient for the user.
23 and 34	Wherein the communications circuitry is configured to telemeter the cardiac electrical signal and the audio signal from the patient-implantable device to the patient-external device in response to a request by the patient-external device.	Gessman (US 5,321,618) teaches of providing transmission in response to a patient-external device at column 4, lines 57-65.	To allow transmission at a time that is convenient for the user.
24, 43, and 47	Wherein the communications circuitry is configured to telemeter the cardiac electrical signal and the audio signal from the patient-implantable device to the patient-external device in real-time.	Gessman (US 5,321,618) teaches of providing the signal in real-time (abstract) because the signal is transmitted over telephone, which operates in real-time.	To provide immediate/current information on the state of the patient.
31	Wherein the user interface comprises a speaker configured to broadcast the audio signal.	Gessman (US 5,321,618) teaches of providing a speaker (Figure 1, element 12).	To transfer the signal in a way that is perceivable by humans (col. 1, lines 36-53).

15	Further comprising a patient actuatable trigger configured to communicate a trigger signal to the controller via the communications circuitry, the controller initiating storing of the cardiac electrical signal and the audio signal in the memory in response to the trigger signal.	Riff (US 2002/0026223) teaches of providing a patient-actuatable trigger (par. 0026).	To provide current cardiac information when a user desires (par. 0026).
26, 42, and 48	Further comprising a server communicatively coupled to one of the patient-implantable device and the patient-external device.	Riff (US 2002/0026223) teaches of providing a server (113) in communication with the implantable device and a patient external device (102 and 118).	To store large amounts of data accessible to many people (par. 0005-0007).
27	Further comprising a server communicatively coupled to the patient-implantable device and the patient-external device.	Riff (US 2002/0026223) teaches of providing a server (113) in communication with the implantable device and a patient external device (102 and 118).	To store large amounts of data accessible to many people (par. 0005-0007).
28	Further comprising a server communicatively coupled to the patient-implantable device and the patient-external device, wherein the cardiac electrical signal and the audio signal are telemetered from the patient-implantable device to the server and communicated from the server to the patient-external device.	Riff (US 2002/0026223) teaches of providing a signal from an implanted device to the server (Fig. 1A, 102 to 112) and from the server to the patient-external device (112 to 118).	To maintain the server in an updated/current state and provide accurate information to the external device.
29	Further comprising a server communicatively coupled to	Riff (US 2002/0026223)	To allow the user to view/check the data

	the patient-external device, wherein the cardiac electrical signal and the audio signal are telemetered from the patient-implantable device to the patient-external device and communicated from the patient-external device to the server.	teaches of providing data from the implanted device to the patient-external device to the server (Fig. 1A, 102 to 104 to 112).	before it is sent to the server.

(10) Response to Argument

A. The rejection under 35 U.S.C. 102(b) of Claims 1-3, 5-7, 9, 10, 12, 13, 16, 17, 19-21, 25, 30, 32, 35, 37-39, 41, and 44-46 is improper because Schaldach fails to teach each of the claimed limitations.

1. Independent claim 17:

Appellant argued that Schaldach is lacking a disclosure of communicating an audio signal that represents a cardiac non-electrophysiologic activity to a patient-external device. However, Schaldach discloses manipulating various combinations of sensed variables with the external display (see col. 23, lines 20-65; col. 26, line 18-col. 27, line 29). An example of which is sensed using the "pressure or sound pickups" of column 7, line 60. This is further specifically indicated at column 26, lines 63-68, wherein Schaldach discloses displaying a figure based on the PEP (which is a variable determined with a mechanical/audio sensor). Regardless of the fact that these signals sensed with a "sound pickup" are presented to a user in visual form, the Examiner maintains that this is an "audio signal" that is communicated to a patient-external device. For the variables to be displayed on an external device (which Schaldach clearly discloses), it is necessary that these signals be transferred from the internal

device, and this is accomplished via the telemetry interface (151). Further, the Examiner maintains the assertion that a visual representation of the audio signal is an "audio output" under the broadest reasonable interpretation. The "audio output" does not require that the output be capable of being heard by a human ear any more than the "audio signal", which is transferred over wires and an RF telemetry interface, be capable of being heard by a human ear. Since the "audio signal" of Appellant's invention is clearly not capable of being heard, for example over the telemetry interface, the modifier "audio" does not require that the signal be capable of being heard by an ear. For example, it is not unreasonable to consider the tracing of an oscilloscope connected to a microphone as an "audio output".

2. Dependent claim 35

Appellant argued that the accelerometer disclosed by Schaldach is used to detect patient activity, and not to provide an actual acceleration signal. Further, Appellant argued that this signal is not capable of being heard by the human ear. However, the heart is part of the body, so detecting movement of the body detects movement of the heart. Since the "characteristic field" is displayed to the user via element 157, and this "characteristic field" comprises the accelerometer signal (which detects movement of the heart), the Examiner maintains the previous rejection. Further, the "pressure or sound pickups" of Schaldach's column 7 measure the accelerations of their surrounding media (whether tissue, blood, etc.), rendering them "accelerometers".

3. Dependent claims 30 and 38

Appellant argued that concurrent display of variables, as taught by Schaldach, does not anticipate the claim limitation that the signals be "time correlated" because a skilled artisan would not interpret the term "time correlated" to mean that two signals are displayed on a monitor at the same time. However, Schaldach discloses that two "characteristic fields", such the audio and electrical signals, can be displayed along with a time axis (col. 23, lines 39-65), rendering the variables "time correlated".

B. The rejection under 35 U.S.C. 103(a) of claims 17, 19-21, 41, 45, and 46 fails to correspond to the claimed invention and the requisite evidence of motivation to combine the references as asserted has not been established.

Appellant argued that the obviousness rejection of claim 17 is an impermissible evocation of Official Notice because there is no evidence of instant and unquestionable demonstration of a device to "implantably produce and store an audio signal, transfer the audio signal to a patient-external device, and to provide an audio output of the audio signal". However, the Examiner merely asserted that it is known in the art to "provide audio signals representative of the audio events of the heart" (see Office Action 2/17/2006, paragraph 19), and supplied several references which teach this principle. Schaldach provides the teaching of the other claim limitations, e.g., "implantably produce and store an audio signal, transfer the audio signal to a patient-external device".

Appellant further argued that there exists no motivation to modify Schaldach because Schaldach is not concerned with "diagnosing cardiac maladies", but with controlling a cardiac pacing device. However, this control is based on diagnosing a problem/less-than-optimal performance of the heart, and then correcting this with the

help of a physician's control or closed-loop control. As such, the Examiner considers this to be analogous to the problem-solving areas of the cited art.

C. The rejection of dependent Claims 4 and 36 is improper because the asserted combination of Schaldach and Turcott fails to teach or suggest each of the claimed limitations and the requisite evidence of motivation to combine the references as asserted has not been established.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, a skilled artisan will recognize the obvious interchangability of mechanical transducers, such as piezoelectric transducers, and Turcott further indicates the motivation of detecting a frequency conducive to heart sound sensing, as indicated above and the Office Action of 2/17/2006.

D. The rejection of dependent Claims 8, 11, and 40 is improper because the asserted combination of Schaldach and Kadhiresan fails to teach or suggest each of the claimed limitations and the requisite evidence of motivation to combine the references as asserted has not been established.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner maintains the motivation to combine Schaldach and Kadhiresan set forth in the Office Action of 2/17/2006, and indicated above.

E. The rejection of dependent Claims 14, 18, 22-24, 31, 33, 34, 43, and 47 is improper because the asserted combination of Schaldach and Gessman fails to teach or suggest each of the claimed limitations and the requisite evidence of motivation to combine the references as asserted has not been established.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner maintains the motivation to combine Schaldach and Gessman set forth in the Office Action of 2/17/2006, and indicated above.

In response to the argument that Gessman fails to teach the limitations of claims 18 and 23, Gessman is not relied upon for a teaching of providing a visual output representative of an audio signal (claim 18) because Schaldach discloses this limitation. In regards to claim 23, please see above and note that the user must utilize an external device (col. 4, lines 57-65) to initiate communication.

F. The rejection of dependent Claims 15, 26-29, 42, and 48 is improper because the asserted combination of Schaldach and Riff fails to teach or suggest each of the claimed limitations and the requisite evidence of motivation to combine the references as asserted has not been established.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner maintains the motivation to combine Schaldach and Riff set forth in the Office Action of 2/17/2006, and indicated above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Michael Kahelin

7/9/07

Conferees:

Angela Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

H. Shackelford